



Enanta
Pharmaceuticals
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**Phase 2a Human Challenge Study of EDP-323:
Topline Results**

Conference Call and Webcast









September 26, 2024

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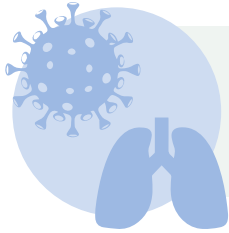
Enanta Pipeline

PRODUCT CANDIDATE			DISCOVERY	PRECLINICAL	PHASE 1	PHASE 2	PHASE 3	MARKET
Virology: Liver	HCV	Protease Inhibitor	Glecaprevir* 					
	HBV	Core Inhibitor	EDP-514** 					
Virology: Respiratory	RSV	N-Protein Inhibitor	Zelicapavir (EDP-938) 					
		N-Protein Inhibitor	Zelicapavir (EDP-938) 					
	L-Protein Inhibitor	EDP-323 						
COVID-19	3CL Protease Inhibitor	EDP-235** 						
Immunology	CSU	KIT Inhibitor						
	Various	Undisclosed						

*Fixed-dose antiviral combination contains glecaprevir and AbbVie's NS5A inhibitor, pibrentasvir. Marketed by AbbVie as MAVYRET® (U.S.) and MAVIRET® (ex-U.S.).

**Continued development dependent on a future collaboration.

Respiratory Syncytial Virus (RSV)



Causes severe lung infections, including bronchiolitis (infection of small airways in the lungs) and pneumonia. Leading cause of hospitalization in infants¹. No safe and effective treatments.

Populations at higher risk for severe illness:

- Pediatrics (infants and children)
- High-risk adults (>65 yrs, COPD, asthma, CHF)
- Immunocompromised (e.g. HIV, transplant)

Significant unmet need for antiviral treatment despite availability of prophylaxis:

- Adoption of adult vaccines is sub-optimal and not recommended for all FDA-approved patient groups*
 - Peak adoption of vaccines for elderly range from ~35% (shingles⁴) to ~55% (flu⁵)
- Pediatric prophylaxis approaches provide passive immunity; will shift first infection to next season
 - Antibody approach has a low barrier to resistance
- Even with adoption, breakthrough infections will still occur

*FDA-approved for adults age ≥60 & 50-59 years who are at increased risk for LRTD caused by RSV^{6,7}
 ACIP-recommended for adults age ≥75 years and age 60-74 years at increased risk of severe RSV⁸

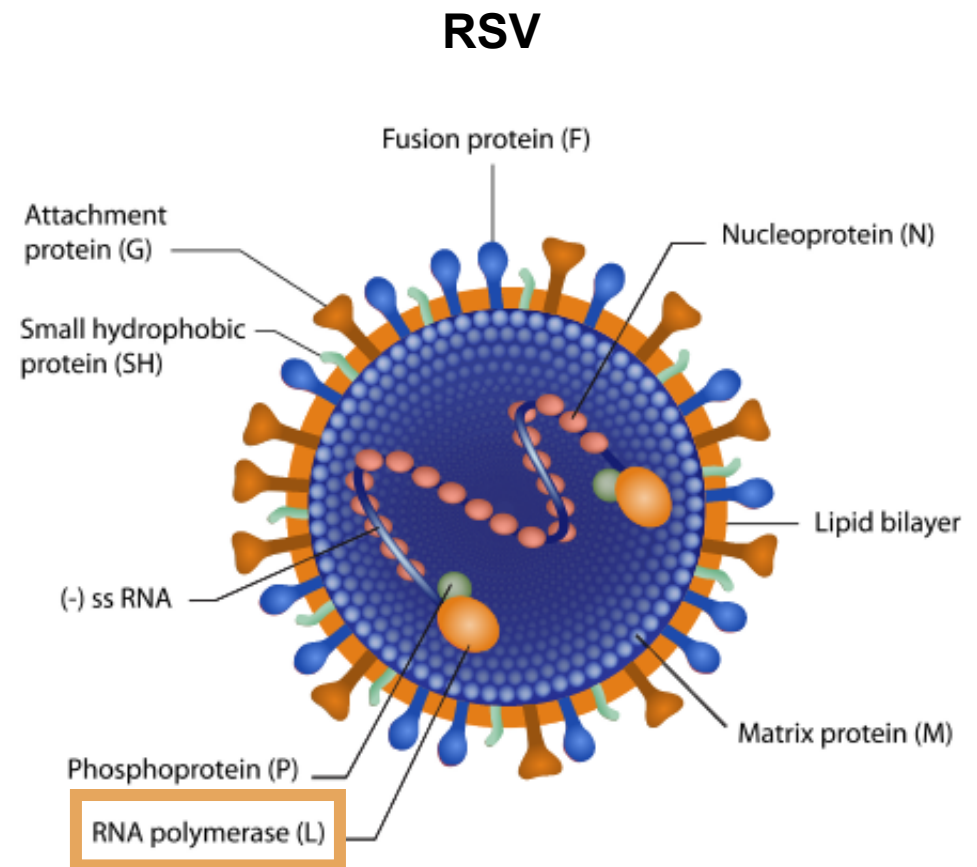
RSV at a Glance

Children < 5 years ²	Adults > 65 years ³
33M global cases	
3M global hospitalizations	177K U.S. hospitalizations
101K global deaths	14K U.S. deaths

Sources: 1. <https://www.cdc.gov/rsv/infants-young-children/index.html> ; 2. [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(22\)00478-0/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(22)00478-0/fulltext) 3. <https://pubmed.ncbi.nlm.nih.gov/15858184/> ; 4. <https://www.cdc.gov/nchs/products/databriefs/db370.htm>: 33.4% in 2016 & 34.5% in 2018 for Age 60+
 5. <https://www.cdc.gov/flu/fluview/dashboard/vaccination-coverage-adults-65-over.htm>: 54% 2021-2022; 58% 2020-2021; 56% 2019-2020 for age 65+
 6. [Pfizer approved label](#) 7. [GSK approved label](#) 8. [ACIP recommendation](#)

EDP-323: RSV L-Protein Inhibitor

- Direct-acting antiviral targeting the L-protein
- Granted Fast Track designation by the FDA
- Potential to be used alone or in combination
 - Additive to synergistic activity with zelicapavir
 - No cross resistance expected with other mechanisms
- Sub-nanomolar potency against RSV-A and B
- Protects mice in a dose-dependent manner from RSV infection
- Phase 1 supported 200 or 600mg once-daily as safe and efficacious dose
 - Trough plasma concentrations were 11- to 44-fold over protein adjusted EC_{90}

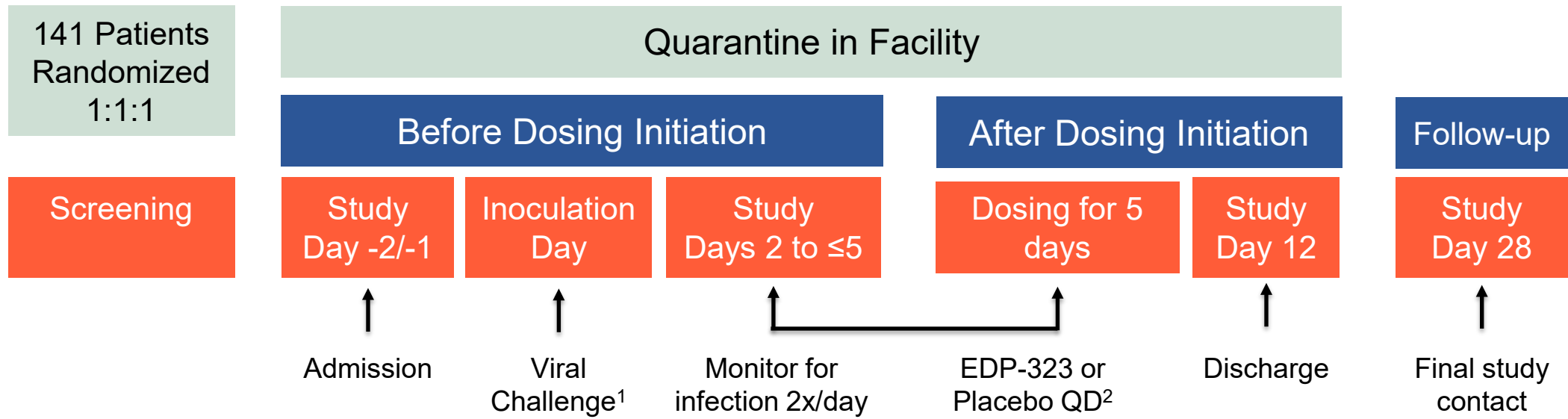


Phase 2a Human Challenge Study of EDP-323: Topline Results

A Phase 2a, Randomized, Double-blind, Placebo-controlled Study To Evaluate The Safety, Pharmacokinetics And Antiviral Activity Of Multiple Doses Of Orally Administered EDP-323 Against Respiratory Syncytial Virus Infection In The Virus Challenge Model In Healthy Adults



EDP-323 Phase 2a RSV Challenge Study Design



Dosing QD for 5 days:

- EDP-323 High Dose – 600mg
- EDP-323 Low Dose – 200mg (with 600mg LD)
- Placebo

Endpoints:

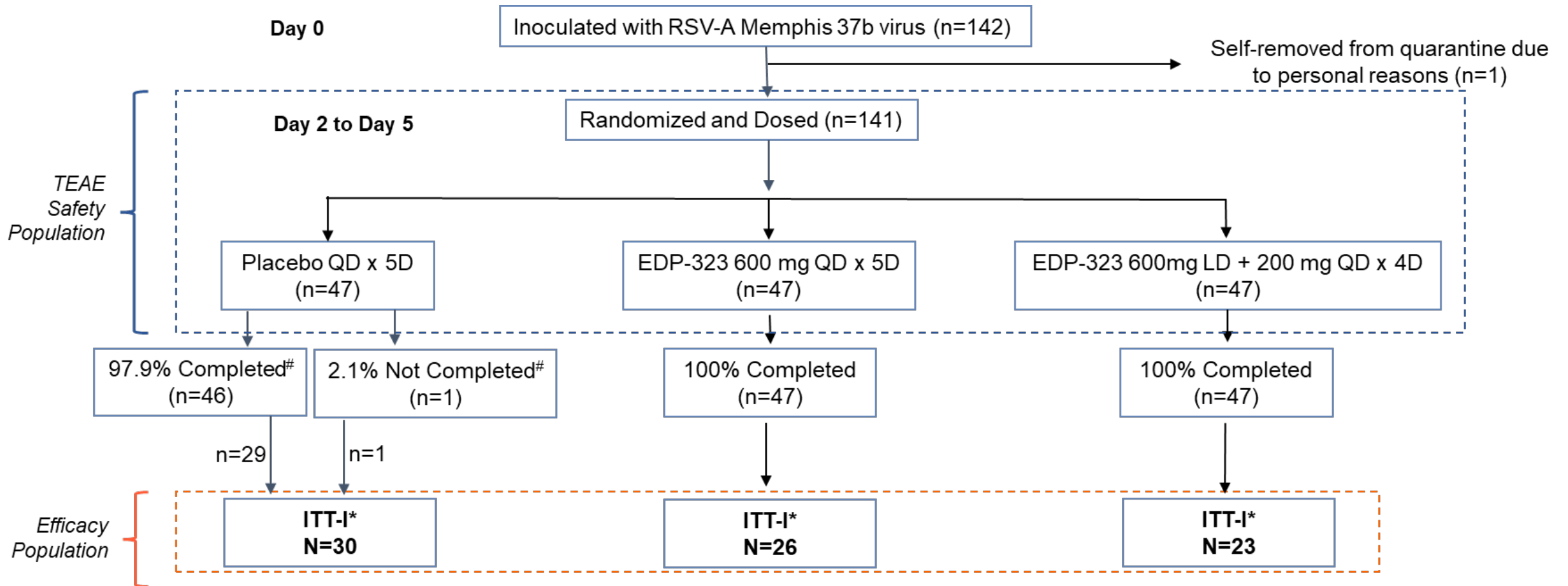
- Primary – RSV Viral Load AUC
- Secondary include
 - RSV Infectious Virus AUC
 - Total Symptom Score AUC

¹ RSV-A Memphis 37b

² Dosing initiated 12 hours after +RSV test (qualitative RT-PCR) or Day 5, whichever was first

AUC: Area Under the Curve; LD: loading dose on Day 1

EDP-323 Phase 2a Study: Participant Disposition



One participant discontinued from the study due to personal reasons on Day 9 after completing the full 5-day dosing period; data from this participant were used in analyses

* **Primary Efficacy analysis, Intent-To-Treat Infected (ITT-I):** All randomized participants receiving challenge virus and ≥1 dose of study drug and with RSV infection confirmed by RT-PCR

EDP-323 Phase 2a Study: Baseline Characteristics

- Baseline characteristics were balanced across groups

Description	EDP-323 High Dose (N=47)	EDP-323 Low Dose (N=47)	Placebo (N=47)
Age: Years – Median (Q1, Q3)	28 (24, 33)	26 (24-30)	27 (23-30)
Sex: Female – n (%)	15 (31.9)	17 (36.2)	19 (40.4)
Race: White – n (%)	39 (83.0)	35 (74.5)	38 (80.9)

Phase 2a Human Challenge Study of EDP-323: Topline Safety & Pharmacokinetic Results



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EDP-323 Demonstrated Favorable Safety Profile & Achieved Target Exposure Levels in Human Challenge Model

- EDP-323 demonstrated a favorable safety profile over a 5-day dosing period and through 28 days of follow-up
- No serious adverse events, no severe adverse events, and no adverse events leading to treatment discontinuation or study withdrawal
- Adverse events were similar between EDP-323 dosing groups and placebo
- No specific pattern of treatment-emergent adverse events was identified

Description	EDP-323 High Dose (N=47)	EDP-323 Low Dose (N=47)	Pooled EDP (N=94)	Placebo (N=47)
Any treatment emergent AEs	11 (23.4%)	14 (29.8%)	25 (26.6%)	13 (27.7%)
Any treatment emergent AEs considered related to study treatment	1 (2.1%)	1 (2.1%)	2 (2.1%)	0 (0.0%)

- EDP-323 mean trough plasma concentrations were maintained at 16- to 35-fold above the protein adjusted EC₉₀ against both RSV A and B strains

Phase 2a Human Challenge Study of EDP-323: Topline Efficacy Results

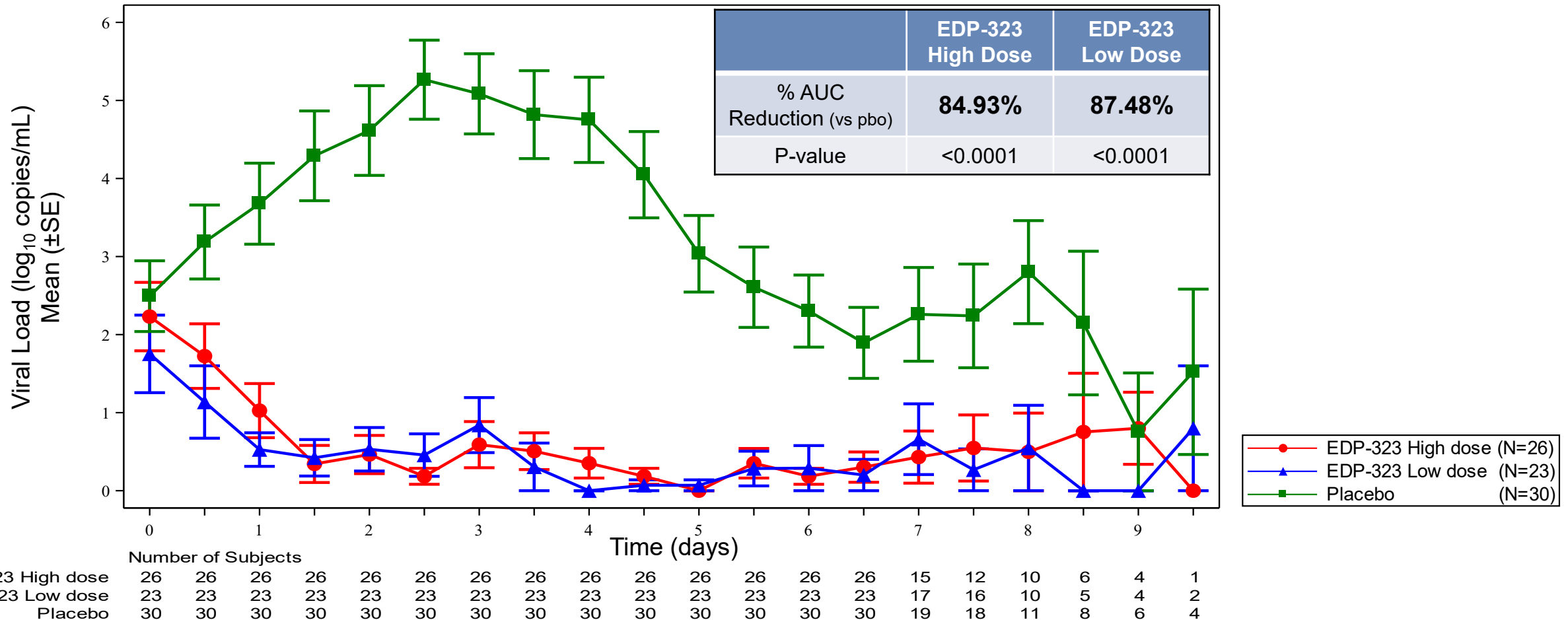


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EDP-323 Results in a Rapid & Sustained Reduction in Viral Load

Primary Efficacy Endpoint: **85-87%** ↓ in VL AUC by qRT-PCR

- Highly statistically significant reductions in VL AUC measured by qRT-PCR compared to placebo
 - No statistically significant difference between the two EDP-323 dosing regimens

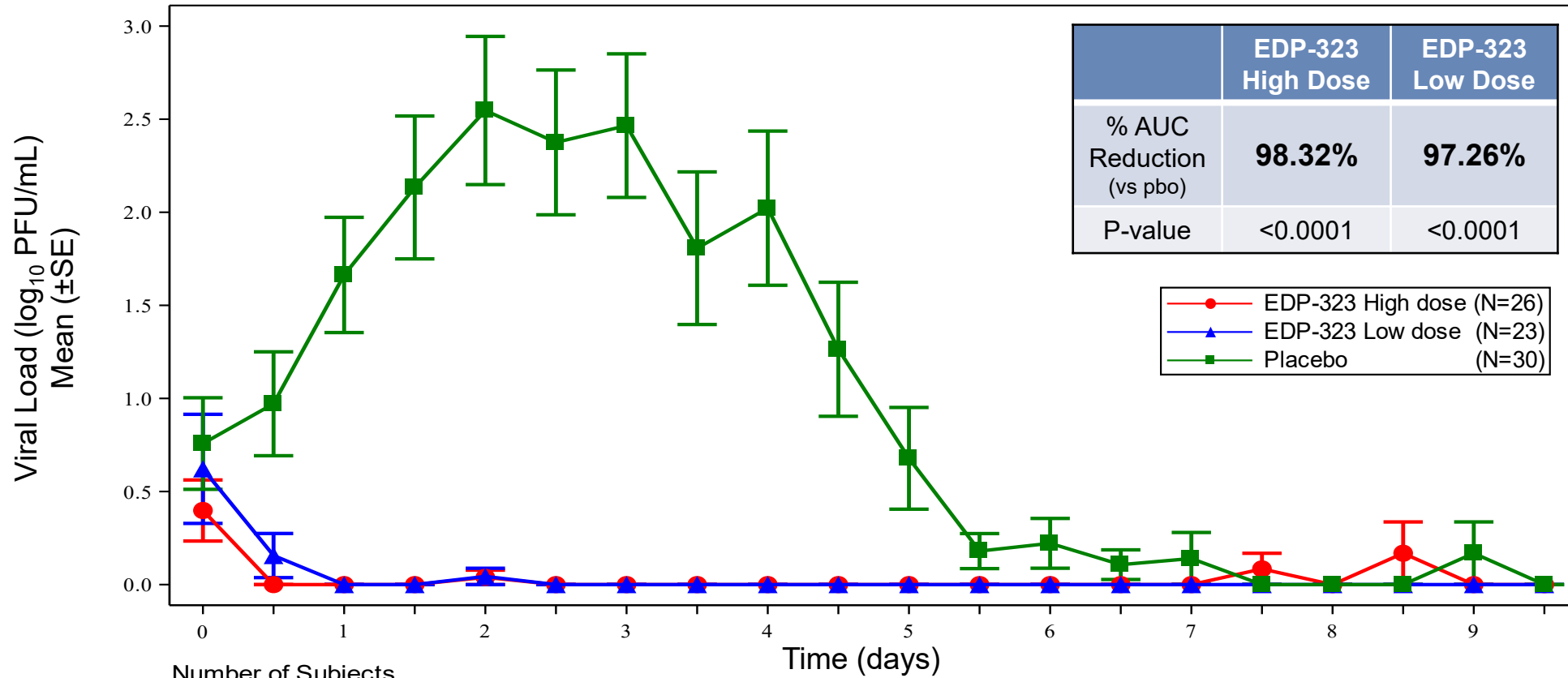


EDP-323 Results in Rapid & Sustained Reduction in Infectious Viral Load

Secondary Efficacy Endpoint: 97-98% ↓ in VL AUC by Viral Culture



- Highly statistically significant reductions in infectious VL AUC measured by quantitative culture compared to placebo
 - No statistically significant difference between the two EDP-323 dosing regimens

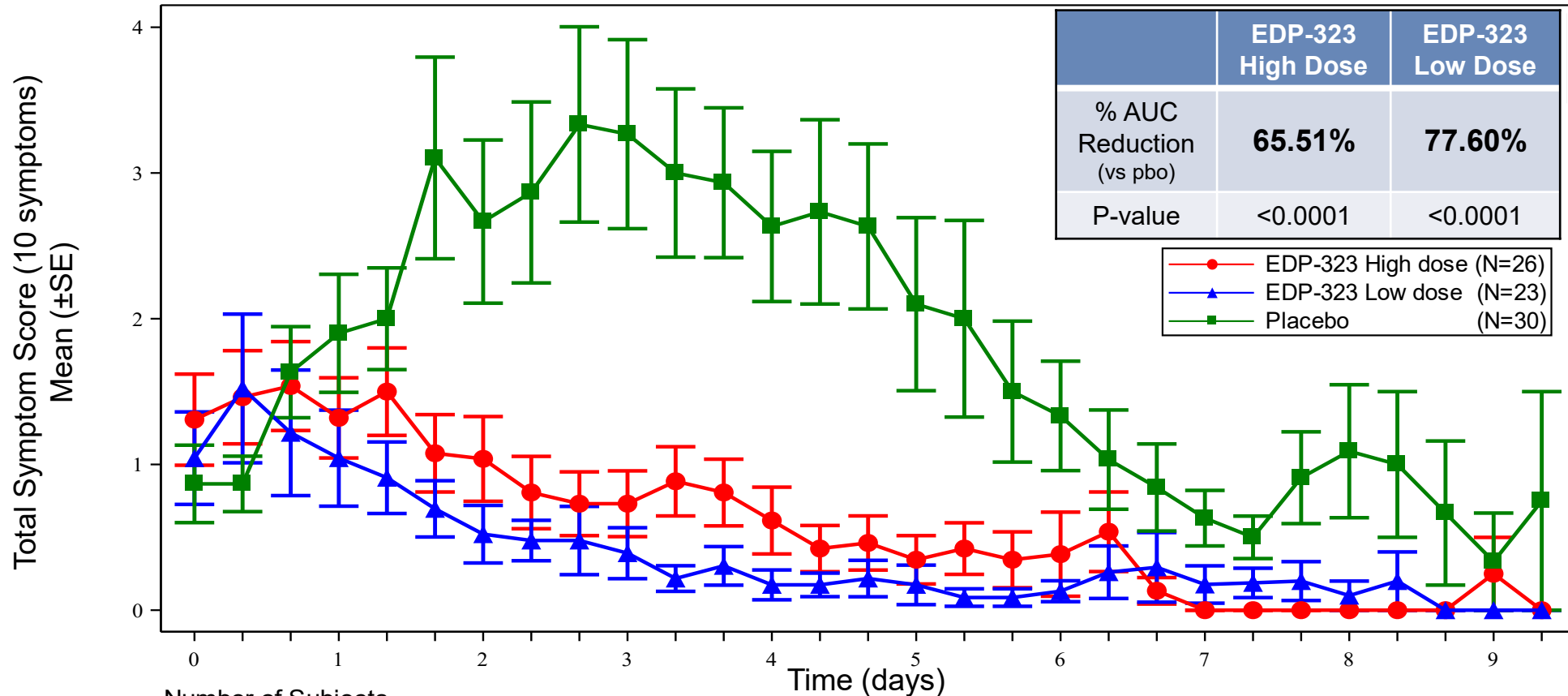


	0	1	2	3	4	5	6	7	8	9
EDP-323 High dose	26	26	26	26	26	26	26	26	15	12
EDP-323 Low dose	23	23	23	23	23	23	23	23	17	16
Placebo	30	30	30	30	30	30	30	30	19	18

EDP-323 Demonstrates Robust Attenuation of RSV Symptoms

Secondary Efficacy Endpoint: **66-78% Reduction in Symptoms**

- Highly statistically significant reductions in TSS AUC in both EDP-323 arms compared to placebo
 - No statistically significant difference between the two EDP-323 dosing regimens



	0	1	2	3	4	5	6	7	8	9	10	
EDP-323 High dose	26	26	26	25	26	26	26	26	26	26	26	26
EDP-323 Low dose	23	23	23	23	22	23	23	23	23	23	23	23
Placebo	30	30	30	30	30	29	30	30	30	30	30	30

EDP-323 Phase 2a RSV Challenge Study: Conclusions

- Well tolerated with safety profile similar to placebo
- Primary & key secondary efficacy endpoints achieved with high statistical significance at both dose levels compared to placebo:
 - Reduction in *viral load* of 85-87%
 - Reduction in *viral culture* of 97-98%
 - Alleviation of clinical *symptoms* by 66-78%
- Data support further clinical evaluation of EDP-323



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